UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

PRISCILLA GARCIA, et al.,

Plaintiffs,

v.

CROWN LABORATORIES, INC.,

Defendant.

Case No. 24-cv-01448-EMC

ORDER ON DEFENDANT'S MOTION TO DISMISS

Docket No. 67

I. INTRODUCTION

Plaintiffs bring a putative class action against Defendant Crown Laboratories, Inc. Consolidated Class Action Complaint ("CAC") ¶¶ 1, 7, 44 (Dkt. 66). Plaintiffs purchased "PanOxyl® branded benzoyl peroxide ('BPO') products (collectively the 'BPO Products')" in various states. *Id.* at ¶ 1. Plaintiffs allege that Defendant's BPO Products "contain benzene and/or degrade to form benzene" and are therefore "worthless." *Id.* at ¶¶ 3, 7. Plaintiffs allege that they reasonably relied on Defendant's representations that BPO Products were "safe, unadulterated, and free of any carcinogens that are not listed on the label." *Id.* at ¶¶ 4. Further, Plaintiffs assert that they "would not have purchased and used the Products at all or would have paid significantly less for them" had they known that the BPO Products contained/degraded to form benzene. *Id.* at ¶¶ 8-43.

Plaintiffs bring seven state law claims against Defendant, all of which are related to the alleged misrepresentation and omission of information on the BPO Products' labelling. Before the

Court is Defendant's motion to dismiss Plaintiffs' CAC for failure to state a claim. Motion to Dismiss (Mot.) (Dkt. 67). For the following reasons, Defendant's motion to dismiss is **STAYED**.

II. BACKGROUND

A. Factual Background

Plaintiffs are residents of California, Missouri, Nevada, New York, Ohio, Pennsylvania, Rhode Island, Washington, Arizona, Massachusetts, Louisiana, Florida, Connecticut, Maryland, and Illinois who purchased "PanOxyl® Acne Creamy Wash Daily Control 4% BPO, PanOxyl® Acne Foaming Wash 10% BPO, and PanOxyl Acne Treatment Bar 10% BPO" (collectively "BPO Products"). CAC ¶ 1, n.1.

Defendant markets, distributes, and sells various skin care products, including those allegedly sold to Plaintiffs in this action. *Id.* at ¶¶ 44-45. Plaintiffs allege that "[a]ll of Defendant's BPO Products are manufactured in the same manner" and that "[a]ll lots of Defendant's BPO Products contain or systematically degrade to form benzene." *Id.* at ¶ 51-52. In support of their allegations, Plaintiffs rely on testing by Valisure LLC ("Valisure"), which tested "sixty-six acne treatment products containing [BPO], all of which tested positive for benzene at various levels," including Defendant's PanOxyl Acne Foaming Wash 10% BPO. *Id.* at ¶ 52. That product was found to contain over 170 ppm benzene. *Id.* Benzene has serious health impacts and is a known carcinogen. *Id.* at ¶¶ 54-69. As a result of their findings, Valisure submitted a citizens petition to the FDA "requesting a recall and suspension of sales" of BPO products from U.S. markets. *Id.* at ¶ 70. "Independent testing conducted on BPO Products purchased by Plaintiffs similarly shows benzene levels significantly above the FDA's recall threshold of 2 ppm." *Id.* ¶ 78. "Benzene is not listed on the BPO Products' labels as an ingredient, nor is there any warning about the inclusion . . . of benzene in the BPO Products." *Id.* at ¶ 124. In 2023, the FDA published an alert to manufacturers regarding the risk of benzene contamination in their products and the need to test their products for the presence of benzene. *Id.* at ¶ 63. Plaintiffs allege that Defendant knew or should have known that its BPO Products contained benzene. *Id.* at ¶ 120. Plaintiffs also allege that "Defendant could have avoided any potential for benzene contamination

in the BPO Products by changing the manufacturing process or raw ingredients, and the BPO Products could have been sold with absolutely no benzene in them." *Id.* at ¶ 105.

Because the BPO Products contain and/or degrade to form benzene, Plaintiffs allege that the products are adulterated or misbranded and therefore illegal to sell. *Id.* at ¶¶ 81-85. Plaintiffs also allege that Defendant violated current Good Manufacturing Practices ("cGMPs"). *Id.* at ¶¶ 89-96, 98. Plaintiffs bring seven claims under various state laws:

First, on behalf of the California subclass, Plaintiffs allege that Defendant violated California's Unfair Competition Law, which prohibits "unfair, deceptive, untrue or misleading advertising." *Id.* at ¶¶ 150-51.

Second, on behalf of the California subclass, Plaintiffs allege that Defendant violated California's Consumer Legal Remedies Act, which prohibits "unfair methods of competition and unfair or deceptive acts or practices in connection with the sale of consumer goods." *Id.* at ¶¶ 162, 164.

Third, on behalf of the California and New York subclasses, Plaintiffs allege that Defendant advertised their BPO Products "with the intent not to sell them as advertised," in violation of various state false advertising statutes. *Id.* at ¶¶ 181-83. California's False Advertising Law prohibits disseminating "untrue or misleading" statements, or statements that should be known to be untrue or misleading through "the exercise of reasonable care." *Id.* at ¶ 182. New York's General Business Law prohibits "[f]alse advertising in the misconduct of any business, trade or commerce or in the furnishing of any service," which includes "advertising, including labeling, of a commodity . . . if such advertising is misleading in a material respect." *Id.* at ¶¶ 182.

Fourth, on behalf of the Arizona, California, Connecticut, Florida, Illinois, Louisiana, Maryland, Massachusetts, Missouri, Nevada, New York, Pennsylvania, Ohio, Rhode Island, and Washington subclasses, Plaintiffs allege that Defendant represented that the BPO Products had "characteristics, uses, and benefits that they did not have," such as the safety, purity, and quality of the BPO Products. *Id.* at ¶ 190. Plaintiffs allege that because Defendant knew or should have known that the BPO Products contain benzene or degrade to form benzene under normal and

expected use, Defendant advertised the BPO Products with the intent not to sell them as advertised. *Id.* at ¶¶ 191-92. Plaintiffs allege such conduct violated several state statutes prohibiting deceptive trade practices. *See id.* at ¶¶ 194-207.

Fifth, on behalf of (1) all consumers who purchased BPO Products directly from Defendant, (2) all consumers whose state law has abrogated the privity requirement for implied warranty of merchantability, and (3) all members of the California subclass, Plaintiffs allege that the representations made by Defendant's labels and accompanying disclosures breached the implied warranty of merchantability. *Id.* at ¶¶ 219-22.

Sixth, on behalf of the nationwide class, Plaintiffs allege that Defendant breached "a common law duty to provide accurate and non-misleading information to consumers with respect to quality, safety, and purity characteristics" of its BPO Products. *Id.* at ¶¶ 232, 238.

Seventh, on behalf of the nationwide class, Plaintiffs allege that Defendant unjustly profited from its deceptive business practices and kept the profits from members of the class that purchased its BPO Products. *Id.* at ¶¶ 246-47.

Plaintiffs seek, *inter alia*: "[a]n order enjoining Defendant from selling the BPO Products;" "[a]n order enjoining Defendant from suggesting or implying that they are safe for human application;" "[a]n order requiring Defendant to engage in a corrective advertising campaign and engage in any further necessary affirmative injunctive relief, such as recalling existing BPO Products;" "[a]n order awarding declaratory relief, and any further retrospective or prospective injunctive relief permitted by law or equity, including enjoining Defendant from continuing the unlawful practices alleged herein, and injunctive relief to remedy Defendant's past conduct;" restitution/damages; disgorgement; and statutory damages. *Id.* at 76-77.

B. Regulatory Background

The BPO Products are nonprescription drugs or over-the-counter ("OTC") drugs to treat acne. The Food and Drug Administration ("FDA") regulates OTC drugs and issues monographs that establish conditions under which an OTC drug is generally recognized as safe and effective for its intended use. *See Nat. Res. Def. Council, Inc. v. U.S. Food & Drug Admin.*, 710 F.3d 71, 75, (2d Cir. 2013) ("Like a recipe, each monograph sets out the FDA-approved active ingredients

for a given therapeutic class of OTC drugs and provides the conditions under which each active ingredient is [generally recognized as safe and effective].”). “Any product [that] fails to conform to each of the conditions contained in … an applicable monograph is liable to regulatory action.” 21 C.F.R. § 330.1.

As Plaintiffs recognize, the FDA’s Acne Monograph regulates the BPO Products. CAC ¶¶ 90, 96. The Acne Monograph has been incorporated into the regulations. *See* 21 C.F.R. § 333.01 to 350 (Acne Monograph). The Acne Monograph provides that an “over-the-counter acne drug product…is generally recognized as safe and effective and is not misbranded” if “it meets each of the conditions in this…chapter.” 21 C.F.R. § 333.301.[1] The Monograph expressly permits the use of benzoyl peroxide (“BPO”) as an active ingredient in products in an amount of 2.5 to 10 percent and imposes labeling and warning requirements for products containing BPO. *Id.* § 333.310. Mandatory warnings are limited to:

> (1) For products containing any ingredients identified in § 330.310.
> (i) The labeling states “For external use only.”
> (ii) The labeling states “When using this product [bullet] skin irritation and dryness is more likely to occur if you use another topical acne medication at the same time. If irritation occurs, only use one topical acne medication at a time.”
> (2) For products containing sulfur identified in § 333.310(e) and (f).
> (i) The labeling states “Do not use on [bullet] broken skin [bullet] large areas of the skin.”
> (ii) The labeling states “When using this product [bullet] apply only to areas with acne.”
> (3) For products containing any combination identified in § 333.320.
> (i) The labeling states “When using this product [bullet] rinse right away with water if it gets in eyes.”
> (ii) The labeling states “Stop use and ask a doctor [bullet] if skin irritation occurs or gets worse.”
> (4) For products containing benzoyl peroxide identified in § 333.310(a).
> (i) The labeling states “Do not use if you [bullet] have very sensitive skin [bullet] are sensitive to benzoyl peroxide.”
> (ii) The labeling states “When using this product [bullet] avoid unnecessary sun exposure and use a sunscreen [bullet] avoid contact with the eyes, lips, and mouth [bullet] avoid contact with hair and dyed fabrics, which may be bleached

[1] *See* 75 Fed. Reg. 9767, 9770 (March 4, 2010) (FDA’s “Topical Acne Drug Products for Over-the-Counter Human Use; Final Rule”) (“We, the Food and Drug Administration (FDA), are issuing this final rule to include benzoyl peroxide as a generally recognized as safe and effective (GRASE) active ingredient in over-the-counter (OTC) topical acne drug products.”)

> by this product [bullet] skin irritation may occur, characterized by redness, burning, itching, peeling, or possibly swelling. Irritation may be reduced by using the product less frequently or in a lower concentration."
> (iii) The labeling states "Stop use and ask a doctor if [bullet] irritation becomes severe."

21 C.F.R. § 333.350(c).

Moreover, OTC drugs are subject to federal current Good Manufacturing Practices ("cGMPs"). The federal cGMP regulations mandate compliance with standards for safety, identity, strength, quality, and purity. 21 U.S.C. § 351(a)(2)(B). Under § 351(a)(2)(B):

> A drug…shall be deemed to be **adulterated**…if it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding **do not conform to** or are not operated or administered in conformity with **current good manufacturing practice** to assure that such drug meets the requirements of this chapter as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess;

21 U.S.C. § 351 (emphasis added). Conversely, it may be implied from this that if the drug conforms with the current good manufacturing practice, it is not "adulterated."

Certain states have adopted federal cGMP regulations in their respective equivalents of the federal Food, Drug, and Cosmetic Act ("FDCA"). For example, California's state equivalent is the Sherman Food, Drug, and Cosmetic Laws ("Sherman Law"). California Health & Safety Code § 110105 of the Sherman Law provides:

> **All good manufacturing practices regulations** for any food, drug, device, or cosmetic and any amendments to the **regulations adopted pursuant to the federal act** in effect on November 23, 1970, or adopted on or after such date, **are the good manufacturing practices regulations of this state.** If the department finds that it is necessary for the protection of consumers, it may adopt interpretative regulations as necessary to define "current good manufacturing practice" as used in this part.

Cal. Health & Safety Code § 110105 (emphasis added).

C. Procedural Background

Plaintiffs filed their Complaint on March 8, 2024. Dkt. 1.

During the parties' initial case management conference on September 17, 2024, the Court issued a stay on discovery. Dkt. 45.

Plaintiffs filed their Consolidated Class Action Complaint ("CAC") on October 25, 2024. Dkt. 66.

Before the Court is Defendant's Motion to Dismiss Plaintiffs' CAC. Dkt. 67.

III. LEGAL STANDARD

A. Failure to State a Claim (Rule 12(b)(6))

Federal Rule of Civil Procedure 8(a)(2) requires a complaint to include "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). A complaint that fails to meet this standard may be dismissed pursuant to Rule 12(b)(6). *See* Fed. R. Civ. P. 12(b)(6). To overcome a Rule 12(b)(6) motion to dismiss after the Supreme Court's decisions in *Ashcroft v. Iqbal*, 556 U.S. 662 (2009) and *Bell Atlantic Corporation v. Twombly*, 550 U.S. 544 (2007), a plaintiff's "factual allegations [in the complaint] 'must . . . suggest that the claim has at least a plausible chance of success.'" *Levitt v. Yelp! Inc.*, 765 F.3d 1123, 1135 (9th Cir. 2014). The court "accept[s] factual allegations in the complaint as true and construe[s] the pleadings in the light most favorable to the nonmoving party." M*anzarek v. St. Paul Fire & Marine Ins. Co.*, 519 F.3d 1025, 1031 (9th Cir. 2008). But "allegations in a complaint . . . may not simply recite the elements of a cause of action [and] must contain sufficient allegations of underlying facts to give fair notice and to enable the opposing party to defend itself effectively." *Levitt*, 765 F.3d at 1135 (quoting *Eclectic Props. E., LLC v. Marcus & Millichap Co.*, 751 F.3d 990, 996 (9th Cir. 2014)). "A claim has facial plausibility when the Plaintiff pleads factual content that allows the court to draw the reasonable inference that the Defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678. "The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Id.* (quoting *Twombly*, 550 U.S. at 556).

IV. DISCUSSION

A. Federal Preemption

Under the Supremacy Clause, "Congress has the power to preempt state law." *Crosby v.*

Nat'l Foreign Trade Council, 530 U.S. 363, 372 (2000); *see also Oneok, Inc. v. Learjet, Inc.*, 135 S.Ct. 1591, 1595 (2015). Congress may exercise this power by expressly providing for preemption. *Crosby*, 530 U.S. at 372. Preemption need not, however, be express; it also occurs "[w]hen Congress intends federal law to occupy the field." *Id.* Additionally, federal statutes will preempt state law that conflicts with federal law. *Id.* Conflict preemption can arise where it is impossible for a party to comply with both state and federal law (*see, e.g., Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142–43 (1963)) or where "the challenged state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Crosby*, 530 U.S. at 373 (*citing Hines v. Davidowitz*, 312 U.S. 52, 66–67 (1941)).

Two presumptions regarding preemption guide the courts. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996). First, courts "start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress," because "the States are independent sovereigns in our federal system," *i.e.*, there is a starting presumption "that Congress does not cavalierly pre-empt state-law causes of action." *Id. See Wyeth v. Levine*, 555 U.S. 555, 565 (2009); *New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 654–55 (1995); *Astiana v. Hain Celestial Grp., Inc.*, 783 F.3d 753, 757 (2015). Second, the "ultimate touchstone" in every preemption case is Congressional purpose and intent. *Medtronic*, 518 U.S. at 485. "Congressional intent to preempt state law must be clear and manifest." *Indus. Truck Ass'n, Inc. v. Henry*, 125 F.3d 1305, 1309 (9th Cir.1997). *See United States v. Locke*, 529 U.S. 89, 108 (2000); *Astiana*, 783 F.3d at 757.

1. Benzene Warning on Label

The Federal Food, Drug, and Cosmetic Act ("FDCA") expressly preempts Plaintiffs' claims that Defendant should have disclosed the presence or risk of benzene on their BPO Product labels. *See* CAC ¶ 7 ("Defendant is . . . liable to Plaintiffs . . . for misrepresenting and/or failing to disclose or warn consumers that the BPO Products contain benzene and/or degrade to form benzene.").

The FDCA, 21 U.S.C. § 301, *et. seq.*, establishes national uniform labeling requirements for food, drugs, and cosmetics. To preserve "[n]ational uniformity for nonprescription drugs" or

over-the-counter ("OTC") drugs, § 379r(a)(2) expressly prohibits any state from establishing "any requirement" that "is different from or in addition to, or that is otherwise not identical with, a requirement under this chapter." 21 U.S.C. § 379r. A "requirement" includes "any requirement relating to public information or any other form of public communication relating to a warning of any kind for a drug." *Id.* § 379r(c)(2). Consequently, the FDCA preempts state law claims imposing requirements that differ from those imposed by the FDCA. *See Kroessler v. CVS Health Corp.*, 977 F.3d 803, 808 (9th Cir. 2020) ("[P]rivate plaintiffs may bring only actions to enforce violations of state laws imposing requirements **identical** to those contained in the FDCA.") (emphasis added) (internal citation omitted). "So if a product's label complies with the Act, then the Act preempts any state-law claim that the product is mislabeled." *Scheibe v. ProSupps USA, LLC*, No. 23-3300, 2025 WL 1730272, at *3 (9th Cir. June 23, 2025).

"[T]o state a 'plausible' mislabeling claim that is not preempted, [Plaintiffs] must plead facts that 'allow[] the court to draw the reasonable inference…that the [BPO Products are] not only mislabeled under state law, but also *misbranded under the [federal] Act*." *Id.* (citing *Iqbal*, 556 U.S. at 678) (emphasis added). "To establish its affirmative defense of preemption on a motion to dismiss, [Defendant] must show that [Plaintiffs'] complaint fails to support that inference." *Id.* Defendant "may establish preemption if [they] prove[] that the [products'] labeling complies with the Act." *Id.* at *5 (9th Cir. June 23, 2025).

Defendant has established preemption under § 379r(a) in the case at bar. Through their state law claims, Plaintiffs seek disclosure of "benzene on the BPO Products' labels or otherwise [a] warning…about its presence." CAC ¶ 3. Section 379r(a) preempts Plaintiffs' state law claims because including a warning about benzene and its risks would impose a requirement that is not "identical to those contained in the FDCA." *Kroessler*, 977 F.3d at 808 (9th Cir. 2020). As stated, the Acne Monograph regulates the BPO Products and clearly specifies the mandatory labeling requirements. *See* 21 C.F.R. § 333.350(c). Notably, none of these requirements impose a duty to include a warning about benzene or its risks. Thus, the FDA specifically identifies the warnings that must be provided for acne drugs containing BPO and these provisions impose no requirement to include warnings of benzene or its risks. *See id.* §§ 333.310(c) and

333.350(c)(1)(i)-(ii), (c)(4)(i)-(iii). Plaintiffs have not demonstrated that the BPO Products at issue fail to comply with the labeling requirements of the FDCA. Plaintiffs instead seek to require warnings different from and additional to those required by the FDCA, warnings not "identical to those contained in the FDCA." *Kroessler*, 977 F.3d at 808 ("[P]rivate plaintiffs may bring only actions to enforce violations of state laws imposing requirements identical to those contained in the FDCA."). As such, FDCA § 379r(a) preempts Plaintiffs' state law claims seeking disclosure of or a warning about benzene or its risks.

Many courts that have addressed the issue have held that § 379r(a) preempts consumer claims seeking to mandate under state law disclosure of benzene or its risks. For example:

- *Howard v. Alchemee, LLC*, 2024 WL 4272931, at *10 (C.D. Cal. Sept. 19, 2024) ("Plaintiffs seek to require Defendants to make disclosures not required under the FDCA that would conflict with the FDA's conclusion that BPO is safe and effective. Because Plaintiffs' claims would impose requirements that differ from and are in addition to those in the FDCA, they are preempted under § 379r.");
- *O'Dea v. RB Health (US) LLC*, 2025 WL 1212835, at *7 (C.D. Cal. Apr. 22, 2025) ("Because the FDCA and the FDA's regulations establish no…limit" on "selling acne medications containing more than 2 ppm of benzene," Plaintiffs' claims seek to impose a restriction that is "different from or in addition to, or that is otherwise not identical with" the requirements of the FDCA" and "[t]heir claims are therefore expressly preempted and must be dismissed.");
- *Smoter v. Mentholatum Co., Inc*., 2025 WL 273437, at *2 (N.D. Ill. Jan. 17, 2025) ("[T]o the extent the plaintiffs argue the labels of the OXY products should have warned them of the possibility of benzene or included benzene as an ingredient, these claims are preempted by federal law and must fail.");
- *Bodunde v. Walgreens Boots All., Inc.*, 2025 WL 1411306, at *12 (E.D. Cal. May 15, 2025) ("[T]o the extent Plaintiff's claims are based on allegations that Walgreens should have warned about the presence of benzene on Walgreen's BPO product labels, that theory is expressly preempted because it would be an addition not required by federal law."

(internal citation omitted);

- *Eisman v. Johnson & Johnson Consumer, Inc.*, 2025 WL 241024, at *4 (C.D. Cal. Jan. 17, 2025) ("Whether Eisman's theory of liability is that the presence of benzene requires a disclosure that Defendants omit, or that it renders the Products adulterated and misbranded, each of his claims seeks to impose requirements that are 'different from or in addition to, or that are otherwise not identical with the FDA's.") (internal citation omitted).

These rulings are hardly surprising because a ruling otherwise would allow state-mandated labels to contradict the FDA's determination that BPO is safe and effective.[2] *See Silva v. Haleon US Inc.*, 758 F. Supp. 3d 1082, 1088 (N.D. Cal. 2024) ("With respect to the labeling of over-the-counter ("OTC") drugs, 'the whole point of section 379r is that it is not up to private litigants—or judges—to decide what is 'false or misleading.' It is up to the FDA.'") (citing *Eckler v. Neutrogena Corp.*, 238 Cal. App. 4th 433, 454 (Cal. Ct. App. 2015)) (finding that § 379r(a) preempted plaintiffs' claims).

Plaintiffs offer no caselaw demonstrating otherwise. In *Ebner v. Fresh, Inc.*, the Ninth Circuit held that § 379r(a) did not preempt the plaintiff's claim regarding a cosmetic product because the plaintiff sought to enforce a law "identical to [the] federal duty under the FDCA: the duty to avoid false or misleading labeling." 838 F.3d 958, 965 (9th Cir. 2016).

Plaintiffs' reliance on *Astiana v. Hain Celestial Grp., Inc.* is similarly misplaced. There, the Ninth Circuit held that the FDCA did "not expressly preempt state causes of action predicated on federal cosmetics labeling laws" because "the FDA did not intend to permit indiscriminate use of the word 'natural' on cosmetics labels." *Astiana v. Hain Celestial Grp., Inc.*, 783 F.3d 753, 758 (9th Cir. 2015). But, there is no indication that the cosmetic products at issue in *Astiana* were subject to an FDA monograph. There was no express federal labeling requirement that was contradicted by asserted state law. As *Astiana* noted, the FDA had never issued regulations regarding the use of the term 'natural' on cosmetic labels. *Astiana* is thus readily distinguishable

[2] Plaintiffs may consult the FDA to change the labeling or seek disapproval of the BPO Products. However, Plaintiffs cannot bring suit under state law to impose requirements that differ from federal regulations in violation of § 379r(a).

from the case at bar where the BPO Products at issue *are* subject to the FDA's Acne Monograph which specifies in detail by regulation the required warnings.

This Court joins its sister courts in holding that the FDCA expressly preempts Plaintiffs' state law claims which challenge the omission of warnings on BPO products that are different from and not required by the FDCA and which assert that that the BPO products are not safe and effective as found by the FDCA regulations.

2. cGMP Violations

Next, Plaintiffs assert state law claims that Defendant failed to comply with federal cGMPs and adulteration standards which are incorporated by reference in state regulations. *See* CAC ¶ 98.

a. Some Parallel Claims May Proceed

As noted above, "private plaintiffs may bring only actions to enforce violations of state laws imposing requirements **identical** to those contained in the FDCA." *Kroessler*, 977 F.3d at 808 (emphasis added); *see* 21 U.S.C. § 379r (expressly prohibiting any state from establishing "any requirement" that "is different from or in addition to, or that is otherwise not identical with, a requirement under this chapter"). Accordingly, a plaintiff may bring state law claims for violations of federal standards adopted in state regulations where "the state requirements at issue are identical to their federal counterparts." *Davidson v. Sprout Foods, Inc.*, 106 F.4th 842, 845-50 (9th Cir. 2024), *cert. denied*, 145 S. Ct. 1922 (2025) (finding that a California Sherman Law claim was "expressly permitted" and "not expressly preempted" because the Sherman Law statute incorporated federal regulations by reference and thus enforced a requirement identical to federal standards).

Here, Plaintiffs allege that Defendant violated state regulations incorporating federal cGMPs and adulteration standards by reference. CAC ¶ 87.[3] Specifically, Plaintiffs allege that

[3] "[S]tate…laws impose an independent duty on drug manufacturers to ensure that end purchasers receive drugs that are made in accordance with cGMPs. This duty emanates from each state's adoption or adherence to federal cGMP and adulteration standards, including…parallel state statutes." The fact that there is no federal private right of action under the FDCA (21 U.S.C. § 337(a)) therefore does not preclude a state from providing a cause of action for violation of its

the "BPO Products" are "contaminated and/or adulterated with benzene," which "indicates that there was a critical failure in Defendant's quality control and testing protocols as required by [federal] cGMPs." *Id.* ¶ 98. Plaintiffs provide a long list of thirty-seven state statutes that purport to mirror the FDCA. *Id.* ¶ 87. The Court takes the California statute as an example.[4] Like the California food labeling regulation at issue in *Sprout*, the California good manufacturing practices regulation incorporates federal regulations by reference:

> All good manufacturing practices regulations for any food, drug, device, or cosmetic and any amendments to the regulations adopted pursuant to the federal act in effect on November 23, 1970, or adopted on or after such date, are the good manufacturing practices regulations of this state.

Cal. Health & Safety Code § 110105. Because the California regulation incorporates federal requirements by reference, the California law is identical to the federal requirement on cGMPs. *Sprout*, 106 F.4th at 848. Accordingly, like in *Sprout*, claims under state laws enforcing "standards…identical to the federal standards" are thus not *prima facie* preempted. *Id.* at 849. *See Navarro v. Walgreens Boots All., Inc.*, 2025 WL 1411406, at *14 (E.D. Cal. May 15, 2025) ("[T]o the extent Plaintiffs' state law claims are parallel claims brought for violations of cGMPs, those claims are not categorically preempted.").

b. Claims that Require Interpretation of the FDCA are Impliedly Preempted

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laws provided the state law is not preempted by the FDCA. *See Sprout*, 106 F.4th at 849 ("This case fundamentally differs from *Buckman*, *Perez*, and *Nexus*" because "plaintiffs are claiming violations of California law, the Sherman Law, not the federal FDCA" and "Congress said" that "standards…identical to the federal standards…are not preempted and hence permitted states to adopt them…There is no reason we can perceive why Congress would permit states to enact particular legislation and then deny enforcement by their citizens.").

[4] Plaintiffs cite to California Health and Safety Code § 111260, which provides that a "drug…is adulterated if the methods, facilities, or controls used for its manufacture, processing, packing, or holding do not conform to, or are not operated or administered in **conformity with current good manufacturing practice** to assure that the drug or device meets the requirements of this part as to safety and has the identity and strength, and meets the quality and purity characteristics that it purports or is represented to possess." CAC ¶ 87; Cal. Health & Safety Code § 111260 (emphasis added). As specified, the state's good manufacturing practices derive from those in the FDCA. *See* Cal. Health & Safety Code § 110105.

However, if Plaintiffs' state law claims based cGMP violations require the Court to interpret the FDCA and regulations thereunder, these claims will be impliedly preempted. As noted above implied preemption ("obstruction preemption") arises where "the challenged state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Crosby*, 530 U.S. at 373 (citing *Hines*, 312 U.S. at 67). "What is a sufficient obstacle is a matter of judgment, to be informed by examining the federal statute as a whole and identifying its purpose and intended effects." *Id.*

Here, Plaintiffs' claim based on asserted violations of the cGMPs appear to obstruct the accomplishment and execution of Congress's objectives of: (1) delegating the specifics of generating and enforcing good manufacturing practices to the FDCA which has the expertise to do so, and (2) ensuring national uniformity in the quality of manufacturing of nonprescription drugs.

i. Objectives at Issue

Two federal objectives are at issue here: 1) preserving national uniformity of nonprescription drugs, and 2) deference to the FDA's expertise in realizing the former objective.

The FDCA provides mechanisms to accomplish both objectives. First, Section 379r enables preservation of national uniformity by expressly preempting state requirements that are not identical to federal law.

Second, Section 337(a) bars private enforcement of the FDCA, which empowers the FDA to determine when a violation of the FDCA has occurred. Section 337(a) of the FDCA vests exclusive enforcement authority in the United States. Section 337(a) provides that "all such proceedings for the enforcement, or to restrain violations, of [the Act] shall be by and in the name of the United States." 21 U.S.C. § 337(a). The Supreme Court has held that § 337(a) is "clear evidence that Congress intended that the [FDCA] be enforced exclusively by the Federal Government." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 352 (2001) (finding that the FDCA impliedly preempted private plaintiffs' state law claims to police fraud on the FDA). Thus, "'[b]ecause the FDCA forbids private rights of action under that statute, a private action brought under [other laws] may not be pursued when…the claim would require litigation of the alleged underlying FDCA violation in a circumstance where the FDA has not itself concluded that

there was such a violation.'" *Nexus Pharms., Inc. v. Cent. Admixture Pharmacy Servs., Inc*., 48 F.4th 1040, 1049 (9th Cir. 2022) (citing *PhotoMedex, Inc. v. Irwin*, 601 F.3d 919, 924 (9th Cir. 2010)). While the FDCA allows for the private enforcement of state law identical to the federal law, Congress vested exclusive enforcement of the FDCA in the FDA – thereby ensuring national uniformity and delegating exclusive enforcement to the FDA which has technical expertise in the field.

Third, Congress enacted laws authorizing the FDA to issue regulations for the efficient enforcement of the FDCA, including cGMP regulations, (21 U.S.C. § 371(a)), establishing the federal cGMP regulations (21 U.S.C. § 351(a)(2)(B)), and empowering the FDA with several enforcement mechanisms such as injunctions (21 U.S.C. § 332), penalties (21 U.S.C. § 333), and seizure (21 U.S.C. § 334).

ii. Discussion

Here the long list of cGMPs assertedly violated would appear to require a substantial amount of interpretation. The cGMP requirements asserted herein are extremely general.[5] Below are three examples from cGMP violations in Plaintiffs' complaint and why adjudicating the claim would appear to require the trier of fact to interpret the regulation.

Plaintiffs allege a violation of the federal cGMP regulation on testing and release for distribution. CAC ¶ 96(i); *see* 21 C.F.R. § 211.165(a). This cGMP regulation provides:

> For each batch of drug product, there shall be **appropriate** laboratory determination of **satisfactory conformance** to final specifications for the drug product, including the identity and strength of each active ingredient, prior to release. **Where sterility and/or pyrogen testing** are conducted on specific batches of shortlived radiopharmaceuticals, such batches may be released prior to completion of sterility and/or pyrogen testing, provided such testing is completed **as soon as possible**.

21 C.F.R. § 211.165(a) (emphasis added). When is a laboratory determination "appropriate," such that a manufacturer can be said to have complied with § 211.165(a)? What constitutes "satisfactory conformance"? What kind of "sterility testing" is adequate? How quick is

[5] The ambiguity is logical as the cGMP regulations must be general enough to encompass differences among drugs.

"as soon as possible"? Would the answers depend on the kind of drug at issue? At different times in the drug's life cycle?

Plaintiffs allege a violation of the federal cGMP regulation on retesting of approved components, drug product containers, and closures. CAC ¶ 96(o); *see* 21 C.F.R. § 211.87. This regulation provides:

> Components, drug product containers, and closures shall be retested or reexamined, as **appropriate**, for identity, strength, quality, and purity and approved or rejected by the **quality control unit in accordance with § 211.84 as necessary**, e.g., after storage for **long periods** or after exposure to air**, heat** or other conditions that **might adversely affect the component**, drug product container, or closure.

21 C.F.R. § 211.87 (emphasis added). When is it "appropriate" or "necessary" to retest or reexamine, such that the manufacturer has complied with § 211.87? What constitutes an adequate "quality control unit"? What is a "long Period," what temperature range constitutes "heat," and how substantial must the effect be to be something that "might adversely affect the component"? Again, would the answers vary from drug to drug?

Plaintiffs allege a violation of the federal cGMP regulation on production record review. CAC ¶ 96(l); *see* 21 C.F.R. § 211.192. This regulation provides:

> All drug product production and control records, including those for packaging and labeling, shall be **reviewed and approved** by the quality control unit to determine compliance with all established, approved written procedures before a batch is released or distributed. Any unexplained discrepancy (including a percentage of theoretical yield exceeding the maximum or minimum percentages established in master production and control records) or the failure of a batch or any of its components to meet any of its specifications shall be **thoroughly investigated**, whether or not the batch has already been distributed. The investigation shall extend to other batches of the same drug product and other drug products that **may have been associated with the specific failure or discrepancy**. A written record of the investigation shall be made and shall include the conclusions and followup.

21 C.F.R. § 211.192 (emphasis added). What constitutes a "thorough" investigation, such that a manufacturer can be said to have complied with § 211.87? What process of "review and approval" is sufficient? How does one determine which drugs "may have been associated with the specific

failure" and what degree of probability should be applied? Again, the answers would seem to depend, *inter alia*, on the drug at issue.

As illustrated above, the cGMP-based claims likely require statutory interpretation which may be specific to a particular drug and circumstance. Allowing courts from around the nation to render interpretations on such a broad slate risks a threat to national uniformity in the quality standards applied to the manufacturing of nonprescription drugs. It would also intrude on Congress's delegation of the exclusive enforcement authority to the FDA (21 U.S.C. § 337(a)) which has the expertise to oversee the quality of manufacture of nonprescription drugs through its application and enforcement of the cGMPs and applicable regulations. Permitting local state and federal courts – through the vehicle of state law incorporating these federal standards – to render varying interpretations of highly general provisions of federal law and regulations threatens to frustrate the national uniformity Congress enforced by the FDA as intended for nonprescription drugs (21 U.S.C. § 379r). Thus, Plaintiffs' cGMP-related claims may be impliedly preempted.

By way of contrast, the claim in *Sprout* involved application of federal law (through a parallel state law) which did *not* require interpretation of a broad federal law. The plaintiff in *Sprout* alleged a violation of a Sherman Law statute which enforced a wholesale prohibition on placing nutrient content claims on the front of a baby food package. *See Sprout*, 106 F.4th at 848 (Defendant "nevertheless produced pouches of baby food with labels on the front of the package," in direct violation of the FDA's labeling standard). The violation in *Sprout* was categorical: the defendant either produced pouches of baby food ***with*** nutrient content claims on the front (in violation of federal law), or it produced pouches of baby food ***without*** nutrient content claims on the front. Thus, the court was not required to interpret the regulation at issue. The answer was a clear and simple binary choice. Without the need for interpretation and the attendant risk of variation in that interpretation, allowing the Sherman Law claim to proceed in *Sprout* did not obstruct the accomplishment of the dual objectives of preserving national uniformity and deferring to the FDA's expertise.

As pled, it is impossible to decipher whether Plaintiffs' state-law theory on cGMP violations involves only binary determinations as in *Sprout* or, more likely, requires statutory

interpretation. Thus, at this stage, that question cannot be determined and so the Court allows Plaintiffs' cGMP-based claims to proceed. However, the Plaintiff must be mindful of the high risk of implied preemption if interpretation of the cGMPs is required.

B. Failure to State a Claim

While Plaintiff's cGMP-based claims survive preemption, these claims are likely to be dismissed because Plaintiffs fail to 1) adequately allege that the state statutes enforce requirements that are identical to federal standards (*i.e.* parallelism), and 2) allege with specificity how Defendant has violated each cGMP requirement identified in Plaintiffs' complaint, specificity necessary not only as a matter of fair notice to the defendant and to meet the pleading standard of Rule 9 but also to determine whether the claims are preempted.

1. Parallel Requirements

First, Plaintiffs fail to allege with specificity that the state statutes in Plaintiffs' list impose requirements that are "parallel…to federal requirements," *i.e.* identical to those imposed by federal law. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008) (internal citation omitted). Plaintiffs provide a laundry list of state statutes without demonstrating that these state regulations actually impose requirements identical to federal ones. The Court notes that certain appear to merely bar the sale of 'adulterated' drugs and do not incorporate, as does California law, the federal law. *See* 35 Pa. Stat. § 780-113(a)(1); Ga. Code § 26-3-3(1). Plaintiffs have failed adequately to allege with specificity parallelism of each state law asserted.

2. cGMP Violations

Second, Plaintiffs' allegations regarding Defendant's cGMP violations fail to provide "sufficient allegations of underlying facts to give fair notice and to enable the opposing party to defend itself effectively" as required by Rule 8 and fail to allege with sufficient detail how Plaintiffs were deceived as required to assert fraud under Rule 9. *Levitt*, 765 F.3d at 1135; *Lancaster Cmty. Hosp. v. Antelope Valley Hosp. Dist.*, 940 F.2d 397, 405 (9th Cir. 1991) (Under Rule 9(b), "a pleader of fraud" must "detail with particularity the time, place, and manner of each act of fraud, plus the role of each defendant in each scheme.").

In particular, Plaintiffs list twenty-one cGMP requirements and portions of the regulatory

language of each. CAC ¶ 96. Plaintiffs allege that Defendant's BPO Products "did not conform to its final monograph specifications . . . which demonstrates inadequate production, process, and quality oversight by Defendant." *Id.* at ¶ 97. Then, Plaintiffs allege that Defendant's failure to conform to the cGMP requirements demonstrates a "critical failure in Defendant's quality control and testing protocols as required by the above-referenced cGMPs." *Id.* at ¶ 98. Such a "critical failure" in Defendant's oversight led to the "production, and ultimate sale to consumers, of BPO Products" that were contaminated with benzene. *Id.* In other words, Plaintiffs allege that Defendant *must have* violated one of, if not all of, the twenty-one cGMP standards that they list simply because benzene-contaminated BPO Products were allowed to enter the marketplace. However, Plaintiffs do not assert *how* Defendant violated or deviated from specific cGMP standards and *how* such deviations led to the adulteration of its BPO Products. Because of the lack of specificity, the complaint fails to state claims based on state law under Rule 12(b)(6). *Iqbal*, 556 U.S. at 678; *Twombly*, 550 U.S. at 556.

Moreover, to the extent Plaintiffs assert an omission theory of consumer fraud for omitting or concealing that the BPO Products contained or degraded to contain benzene, Plaintiffs' allegations fail to meet the pleading standard of Federal Rule of Civil Procedure 9(b). One asserting a "fraudulent concealment suit will 'not be able to specify the time, place, and specific content of an omission as precisely as would a plaintiff in a false representation claim'" because "a plaintiff…alleging a failure to act instead of an affirmative act…cannot point out the specific moment when the defendant failed to act." *Baggett v. Hewlett-Packard Co.*, 582 F. Supp. 2d 1261, 1267 (C.D. Cal. 2007) (citing *Falk v. General Motors Corporation*, 496 F.Supp.2d 1088, 1098–99 (N.D. Cal.2007). Thus, "a fraud by omission or fraud by concealment claim "'can succeed without the same level of specificity required by a normal fraud claim.'" *Id.* Nonetheless assertions of omissions cannot be conclusory. Here, Plaintiffs have not alleged facts demonstrating how Defendant violated cGMPs or adulteration standards or how these alleged deviations deceived Plaintiffs (or the consuming public) in any consequential way. Plaintiffs' allegation that "had Defendant adequately tested its BPO Products for benzene, it would have discovered that the Products contained benzene" is too conclusory. CAC ¶ 128.

Finally, greater specificity as to how the cGMPs were violated is necessary to determine whether the alleged violation(s) require interpretation of the cGMP requirements which would implicate implied preemption. Again, theories that require interpretation of the cGMPs rather than a clear binary determination as in *Sprout* would be impliedly preempted.

The Court is inclined to grant Defendant's motion to dismiss. *See Ebrahimi v. Mentor Worldwide LLC*, 804 F. App'x 871, 872 (9th Cir. 2020) (affirming district court's Rule 12(b)(6) dismissal where a plaintiff "essentially contend[ed] that the court can plausibly infer that [a defendant] must have violated at least one of the FDA's CGMPs by not catching her allegedly defective [product]" because "mere allegations suggesting that [the plaintiff's] particular [products] were defective do not show that [the defendant] failed to comply with the FDA's Current Good Manufacturing Practices.") (internal citation omitted); *see also Weber v. Allergan, Inc.*, 940 F.3d 1106, 1114 (9th Cir. 2019 (affirming district court's grant of summary judgment for defendant where "mere evidence suggesting that [the plaintiff's] particular [product] was defective does not show that [the defendant] failed to comply with the FDA's Current Good Manufacturing Practices" and "evidence that some other [products] produced by [the defendant] were defective does not demonstrate noncompliance.").

V. CONCLUSION

Although the Court is inclined to grant Defendant's motion to dismiss, it will permit Plaintiffs to amend their complaint to allege with specificity the parallel state laws it asserts and specific facts establishing Defendant's violations of particular cGMPs and how such violations rendered the BPO Products adulterated, provided that those asserted violations are limited to those which can be proven without interpretation of the cGMPs.

The Court will stay the current motion to dismiss and lift the stay on discovery to permit Plaintiffs the opportunity to conduct limited and focused discovery on the alleged cGMP violations. Such discovery will be limited to written discovery designed to determine whether the cGMPs were violated in a manner that does not require interpretation or scientific/technical judgment, *i.e.* violations provable in a manner similar to that in *Sprout*. Plaintiffs shall have 60

days to conduct such limited and focused written discovery and file any amended complaint consistent with their Rule 11 obligations. Failure to timely file an amended complaint will result in dismissal of this case with prejudice for the reasons stated herein.

IT IS SO ORDERED.

Dated: August 6, 2025

EDWARD M. CHEN
United States District Judge